PRVD2008-15

Proposed Re-evaluation Decision

Metaldehyde

(publié aussi en français)

25 April 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

ISBN: 978-0-662-48596-4 (978-0-662-48597-1)
Catalogue number: H113-27/2008-15E (H113-27/2008-15E-PDF)

© **Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2008**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Overview 1
- What Is the Proposed Re-evaluation Decision? 1
- What Does Health Canada Consider When Making a Re-evaluation Decision? 1
- What Is Metaldehyde? 2
- Health Considerations 2
- Environmental Considerations 3
- Measures to Minimize Risk 4
- Next Steps 4

Science Evaluation 5

1.0 Introduction 5

2.0 The Technical Grade Active Ingredient, Its Properties and Uses 5
- 2.1 Identity of the Technical Grade Active Ingredient 5
- 2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient 6
- 2.3 Comparison of Use Patterns in Canada and the United States 6

3.0 Impact on Human Health and the Environment 7
- 3.1 Human Health 8
  - 3.1.1 Occupational Exposure and Risk Assessment 8
  - 3.1.2 Non-Occupational Exposure and Risk Assessment 9
  - 3.1.3 Cumulative Effects 13
- 3.2 Environment 13
  - 3.2.1 Environmental Risk Assessment 13
  - 3.2.2 Toxic Substances Management Policy Considerations 15

4.0 Proposed Re-evaluation Decision 16

5.0 Supporting Documentation 17

List of Abbreviations 19

Appendix I Registered Products Containing Metaldehyde as of February 2008 21

Appendix II Toxicological Endpoints for Metaldehyde Health Risk Assessments 23

Appendix III Uses and Use Parameters Supported by the PMRA as a Result of the Re-evaluation Decision 25

Appendix IV Label Amendments for the Commercial Class End-Use Product Containing Metaldehyde 27

Appendix V Label Amendments for the Domestic Class End-Use Products Containing Metaldehyde 31

References 35

Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the molluscicide metaldehyde, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing metaldehyde in Canada.

An evaluation of available scientific information found that products containing metaldehyde do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of metaldehyde uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

This proposal affects all end-use products containing metaldehyde registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for metaldehyde and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of metaldehyde.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Metaldehyde, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration

---

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2006 RED and the 2007 amendment to the RED, the USEPA concluded that metaldehyde was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found that the USEPA assessments described in these documents were adequate bases for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Metaldehyde?

Metaldehyde is a molluscicide that is used to control snails and slugs on a wide variety of sites in agriculture and home gardens, including fruit and vegetable crops, ornamentals, lawns and turf. Metaldehyde may be applied with ground equipment by professional applicators. Homeowners can apply metaldehyde by hand to soil surfaces in and around home gardens.

Health Considerations

Can Approved Uses of Metaldehyde Affect Human Health?

Metaldehyde is unlikely to affect your health when used according to the revised label directions.

People could be exposed to metaldehyde by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that metaldehyde was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Metaldehyde is currently registered in Canada for use on asparagus, beans, cabbage, carrots, celery, cucumbers, lettuce, melons, onions, peas, cherries, peaches, apples, blackberries, strawberries and grapes, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for metaldehyde in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Metaldehyde Is Introduced Into the Environment?

Metaldehyde is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic animals and plants) could be exposed to metaldehyde in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of metaldehyde was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of metaldehyde, the PMRA is proposing further mitigation measures to address potential exposures and risks to humans, domestic animals and the environment.

- Prohibition of broadcast and foliar applications
- Prohibition of application to turf and dichondra
- Prohibition of application within 30 cm of food/feed crops for which metaldehyde use is not allowed
- Reduction in maximum application rates and numbers of yearly applications for certain crops
- A restricted-entry interval to protect workers re-entering treated sites
- Enhanced precautionary measures to protect children, domestic animals, and wildlife
- Inclusion of a bittering agent in all domestic class products to deter ingestion of the product by children and domestic animals
- Formulation of granular products to small pellet size (>35 pellets/gram) limit to avoid products being mistaken for pet foods/wildlife forage items

Next Steps

Before making a final re-evaluation decision on metaldehyde, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

---

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Metaldehyde is a molluscicide, which acts by stimulating the mucus-producing cells to overproduce mucus, thus causing dessication and death of slugs and snails.

Following the re-evaluation announcement for metaldehyde, the registrant of the technical grade active ingredient in Canada indicated its intention to provide continued support for certain uses currently registered in Canada.

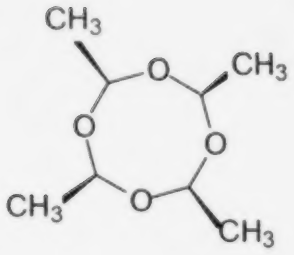
The PMRA used recent assessments of metaldehyde from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for metaldehyde, dated 27 July 2006, and the amendment to the RED, dated 22 June 2007, as well as other information on the regulatory status of metaldehyde in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Metaldehyde
Function	Molluscicide
Chemical family	Cyclooctane
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	*r*-2,*c*-4,*c*-6,*c*-8-tetramethyl-1,3,5,7-tetroxocane; 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane
2. **Chemical Abstracts Service (CAS)**	2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane; acetaldehyde tetramer
CAS Registry Number	108-62-3
Molecular formula	$C_8H_{16}O_4$

Structural formula



Molecular weight	176.2
Purity of the technical grade active ingredient	98% NS (95.06–99.9%)
Registration Number	22689

Based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	1.1×10^{-5} torr
Henry's law constant	3.5 Pa m^3 mol^{-1} (at pH 7 and 25°C)
UV–visible spectrum	Not expected to absorb at $\lambda > 220$ nm
Solubility in water	222 mg/L
n-Octanol–water partition coefficient	log K_{ow} = 0.12 (neutral range and 25°C)
Dissociation constant	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

Metaldehyde is a molluscicide registered in Canada for the control of snails and slugs. It is used on a wide variety of sites in agriculture and home gardens, including fruit and vegetable crops, ornamentals, lawns and turf.

One metaldehyde technical class, one manufacturing concentrate, one commercial class and 13 domestic class products containing metaldehyde are currently registered in Canada. Appendix I lists all metaldehyde products that are registered as of February 2008 under the authority of the *Pest Control Products Act*.

The only Canadian commercial class end-use product containing metaldehyde is formulated as pellets and is applied with ground equipment to the soil such that there is no direct contact with the foliage or edible portions of food crops. The recommended time of application is on a damp evening or following rain or watering during the growing season. A maximum of six applications per year may be made with a rate of up to 1.8 kg a.i./ha on vegetables, tree crops, and small fruit, and 0.9 kg a.i./ha on turf and ornamentals.

The 13 Canadian domestic class end-use products are manufactured in four ready-to-use (RTU) formulations: particulates, pellets, suspensions and granules. They are applied by hand to soil surfaces where pests roam. Application rates and number of applications are various, or the product can be applied as necessary until the pests are under control.

The technical registrant indicated to the PMRA that the support for use and use parameters of metaldehyde on crops in Canada under the PMRA's re-evaluation program will be limited to only those that were supported for the reregistration program in the United States.

Canadian uses that were supported by the registrant and that are subject to this re-evaluation are as follows:

- Canadian commercial uses on blackberries, strawberries, cabbage, lettuce, spinach, tomato, turf and ornamentals

- Canadian domestic uses on turf, dichondra, ornamentals, lettuce, cole crops and other leafy greens, tomato, strawberry, blueberries, caneberries and other berries, and artichoke (this includes all the uses covered in the RED, except citrus, which is not grown in Canada, and grass grown for seed, which is not applicable to the domestic scenario)

Taking into account that the Canadian formulation types of the end-use products and application methods are also encompassed by those considered in the RED, it was concluded that the USEPA RED for metaldehyde can be used as the primary basis for the Canadian re-evaluation and decision making for this active and its associated end-use products.

3.0 Impact on Human Health and the Environment

In its 2006 RED and 2007 amendment to the RED, the USEPA concluded that the end-use products formulated with metaldehyde met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended products and product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to metaldehyde may occur through consumption of food and water, residential exposure, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required. The USEPA's toxicological endpoints for assessing risk from occupational exposure are summarized in Appendix II.

Workers can be exposed to metaldehyde through mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

No toxicological endpoint of concern was identified by the USEPA for the dermal route of exposure to metaldehyde. Therefore, no occupational risk assessment was done for this route of exposure.

Several inhalation exposure scenarios for mixers, loaders, and applicators were assessed in the RED. The following five were considered relevant to the Canadian situation:

- loading granules for tractor-drawn spreader applications
- applying granules via tractor-drawn spreader
- applying granules by hand
- loading/applying granules via belly grinder
- loading/applying granules via push-type spreader

Handler exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED), Version 1.1 for the first four exposure scenarios, and data from the Outdoor Residential Exposure Task Force were used for the fifth exposure scenario.

Short- and intermediate-term inhalation risk assessments were based on maximum supported metaldehyde application rates, ranging from 0.9 to 3.9 kg a.i./ha.

Short- and intermediate-term inhalation MOEs for all occupational handler exposure scenarios were found acceptable (i.e. greater than target MOE of 100). Risks were not of concern at the baseline level of personal protection (i.e. handler wearing long-sleeved shirt, long pants, shoes, and socks), with the lowest MOE being 1500.

The RED adequately addressed potential exposure scenarios associated with the Canadian uses of metaldehyde based on relevant application rates and formulation type. Thus, the conclusions derived from the RED are considered to be applicable to the Canadian situation. The label of the Canadian commercial class end-use product currently contains the requirement to wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves when handling and applying the product. This is considered adequate, and no further mitigation measures are required.

3.1.1.2 Postapplication Exposure and Risk

Occupational postapplication exposures were not assessed for metaldehyde because no dermal hazard was identified and inhalation exposures were assumed to be negligible in outdoor postapplication scenarios due to metaldehyde's low vapour pressure and dilution in outdoor air. Postapplication inhalation exposures for indoor spaces (i.e. greenhouses) were also assumed to be minimal because the Worker Protection Standard for Agricultural Pesticides requires that greenhouses be well ventilated following pesticide application.

The USEPA postapplication risk assessment is considered relevant to Canada because the Canadian uses are encompassed by those of the United States. For greenhouse uses, the PMRA deems that the postapplication exposure is minimal due to metaldehyde's low vapour pressure and the formulation type of the product (pellet) used in the greenhouse scenario. Proposed label amendments are listed in Appendix IV.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure was estimated by the USEPA using the MOE approach as explained in Section 3.1.1 above. The toxicological endpoints selected by the USEPA for assessment of risk from residential exposure are summarized in Appendix II.

Homeowners can be exposed to metaldehyde through mixing, loading and applying the pesticide, and when re-entering a treated site. Toddlers can be exposed following application via "hand-to-mouth" and "object-to-mouth" activities and through incidental soil ingestion.

Eight major handler exposure scenarios were identified by the USEPA. Among those, the following two exposure scenarios were considered to be relevant to the Canadian situation:

- applying granules by hand

- applying RTU liquid/paste formulations via squeeze bottle or tube

To complete the residential handler risk assessments, the following assumptions were used:

- maximum application rates, ranging from 0.9 to 3.9 kg a.i./ha
- the same homeowner completed all tasks associated with the use of the pesticide product wearing shorts and a short-sleeved shirt

As no dermal endpoint of concern was identified for metaldehyde, the USEPA did not assess dermal risks to residential handlers. Intermediate- and long-term inhalation risks were not assessed because of the sporadic nature of applications by homeowners. Short-term inhalation MOEs were greater than the target MOE of 1000 for all scenarios, ranging from 56 000 to 6 000 000, and therefore were not of concern.

Residential postapplication inhalation exposure was expected to be minimal due to the chemical's limited volatility and dilution by ambient air.

The USEPA quantitatively addressed the risks associated with the oral exposures of toddlers who play on treated turf and could potentially be exposed through hand-to-mouth activities, object-to-mouth activities, and ingestion of treated soil. An acceptable MOE of 1600 (i.e. >1000) was calculated for exposure by all three routes combined on the day of application. The USEPA concluded that short-term risks for toddlers from mouthing exposures on treated turf were not of concern.

Children could also be potentially exposed through ingesting metaldehyde formulations. It was determined that ingestion of two mini-pellets or 15 granules would exceed the USEPA's level of concern. However, this scenario was deemed episodic in nature and considered unlikely to occur because of the use of a bittering agent in the formulations. The likelihood of such exposure was expected to be further reduced by the 10-fold increase in the bittering agent required for the metaldehyde home and garden products in the United States since 2003, and also by the mandatory labelling statements that require users to keep children out of areas where the product is stored or used. Metaldehyde exposures to domestic animals, especially dogs, were also of concern to the USEPA.

Multiple mitigation measures were required by the USEPA in the RED and in the amendment to the metaldehyde RED to address the risk of children or domestic animals directly ingesting metaldehyde. These documents adequately addressed potential exposure scenarios associated with the Canadian residential uses of metaldehyde, and the EPA conclusions are considered applicable to the Canadian situation. Based on this, the PMRA requires mitigation measures similar to the United States to mitigate potential exposure of children and domestic animals from direct ingestion of metaldehyde. These requirements for Canadian end-use products include:

- Amendment to domestic class product labels to include graphics and statements similar to the United States to exclude children and pets from treated and storage areas.

- Prohibition of uses on turf and dichondra, and prohibition of broadcast and foliar applications. Currently, there are Canadian metaldehyde products that can be used along pathways. Although this use was not specifically discussed in the RED, this use may lead to the potential exposure of children and animals via oral ingestion, and should also be removed from product labels.

- Reduction of uses on certain crops to be in line with those supported by the USEPA (see Appendix III for PMRA approved use information).

- Requirement to formulate domestic class products with a bittering agent approved by the PMRA at sufficient concentration to deter ingestion by children and domestic animals.

- Improvement of labels regarding poisoning information for users, physicians and veterinarians.

- Amendment to domestic class product labels to include advice on cultural practices, such as watering in the morning instead of evening.

Label amendments are described in detail in Appendix V.

3.1.2.2 Exposure From Food and Drinking Water

Acute dietary risk due to food is calculated considering the highest intake of the chemical residue that would be likely to occur on any given day, using food consumption and food residue values and comparing this potential exposure to an acute reference dose. In the RED, it is expressed as the acute population adjusted dose (aPAD), the dose at which an individual of a particular population subgroup could be exposed on any given day and expect no adverse health effects.

To estimate acute food exposure from all supported metaldehyde food uses, an unrefined Tier 1 assessment was conducted assuming that 100 percent of each commodity was treated (CT) and that all residues were at tolerance levels. The residential exposure for the most highly exposed population subgroup represented 25% of the aPAD, and therefore the risks were below the USEPA's level of concern (LOC).

Chronic dietary risk assessment is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake; that is, the dose at which an individual of a particular population subgroup could be exposed over the course of a lifetime and expect no adverse health effects. The term acceptable daily intake (ADI) is used in Canada, while in the RED, it is expressed as the chronic population adjusted dose (cPAD). The cPAD is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation.

The same assumptions (tolerance level residues, and 100% CT) were used in the chronic food exposure analysis. Exposure for the most highly exposed population subgroup represented 49% of the cPAD, and therefore the risks were below the USEPA's level of concern.

Metaldehyde does not sorb strongly to soils and was expected to be mobile and moderately persistent in the environment. Therefore, it has the potential to contaminate drinking water. The USEPA estimated the drinking water concentrations of metaldehyde for both surface water and groundwater.

Tier I screening computer models were used to generate screening level estimated drinking water concentrations (EDWCs). The highest estimated EDWC from groundwater, 62.5 µg/L, was calculated based on the use of metaldehyde on ornamental plants, assuming a maximum seasonal use rate of 46 kg a.i./ha, and was used for both the acute and chronic dietary risk assessment.

EDWCs from surface water sources were calculated based on use of metaldehyde on Brassica and leafy vegetables in Florida and California assuming a maximum seasonal use rate of 4.5 kg a.i./ha. The maximum estimated peak acute concentration, 110 µg/L, was used for the acute dietary risk assessment. The maximum estimated annual mean concentration, 55.8 µg/L, was used for the chronic dietary risk assessment.

For the most highly exposed population subgroup (children 1–2 years old), the acute dietary exposure estimates were 26 and 29% of the aPAD, using surface water and groundwater, respectively, as a source of drinking water. The estimated combined chronic risks from food and drinking water exposure were also below the USEPA's LOC, taking up 59 and 69% of the cPAD for the most highly exposed population subgroup (children 1–2 years old) using surface water and groundwater as drinking water sources, respectively.

The USEPA assessment is considered to be applicable to the Canadian situation based on the following.

- The supported Canadian agricultural and residential use patterns are encompassed by those in the United States.
- The dietary food exposure was analyzed assuming tolerance level residues and 100% crop treated with metaldehyde; therefore, food exposures/risk would not be underestimated.
- The dietary drinking water assessment utilized values generated by model and associated modelling parameters that were designed to provide conservative, high-end estimates of water concentrations.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk assessment addresses the combined risk from dietary (food and drinking water) exposures and non-occupational exposures. In the case of metaldehyde, the aggregate risks were predicted by the USEPA on acute, short-term and chronic bases.

The acute aggregate risk assessment took into consideration exposures from food and water only. As described in the previous section, the risk estimates were below 100% of the aPAD for the general population and all the population subgroups and were, therefore, not of concern.

Short-term aggregate risk estimates incorporated, in addition to the dietary exposure, the incidental oral exposure of children playing on treated turf and the inhalation exposure of adult handlers. The calculated aggregate MOEs for all scenarios were beyond the target MOE (1000) at 1200 or greater, and not of concern to the USEPA.

There were no long-term residential exposures expected for metaldehyde. Therefore, chronic aggregate risk incorporated only food and drinking water. The chronic dietary (food and water) risks were not of concern as described in the previous section.

Overall, there were no dietary risks nor residential risks of concern. Aggregate risks were also below the USEPA's levels of concern.

The Canadian potential aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of metaldehyde in Canada.

3.1.3 Cumulative Effects

The USEPA has not determined whether metaldehyde has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that metaldehyde does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA concluded that metaldehyde was highly mobile and relatively persistent in the environment and, thus, expected possible leaching of metaldehyde into groundwater. Bioconcentration in aquatic organisms was considered to be low.

The major environmental degradation products of metaldehyde are carbon dioxide and acetaldehyde. Acetaldehyde is readily oxidized into acetic acid and ultimately to carbon dioxide and water in the environment. Exposure to acetaldehyde was not expected to significantly increase the risk to either aquatic or terrestrial wildlife.

Exposure and Risk to Terrestrial Wildlife
The application method considered in this assessment was ground broadcast of metaldehyde granules to soil, and the most common type of exposure of terrestrial animals was expected to be direct ingestion of metaldehyde granules applied to the soil.

Chronic risk of metaldehyde to terrestrial organisms was not assessed by the USEPA because there was no standard methodology at the time of the RED for estimating environmental concentration from granular applications.

Acute risk to terrestrial wildlife from exposure via ground application of granular metaldehyde to soils was estimated using a computer model. The model was run on the assumption that 100% of the applied granules were present on the surface of the soil following application of 0.9 kg a.i./ha to berries and artichokes, 1.1 kg a.i./ha to Brassica, leafy and fruiting vegetables, strawberries, dichondra and turf, and 3.9 kg a.i./ha to ornamental plants.

The Tier I screening level risk assessment showed that avian and mammalian species are at risk from acute exposure to metaldehyde granules for all the use sites considered in the RED at rates ranging from 0.9 to 3.9 kg a.i./ha. Smaller animals are at greater risk than larger animals. Sublethal effects via acute exposure to metaldehyde were also observed in laboratory studies, which may indirectly affect survival. In addition, incident data for domestic animals and wildlife were supportive of these assessment results.

The acute risk was not assessed quantitatively for terrestrial invertebrates due to lack of data. However, impact to terrestrial mollusk populations and possibly carabid beetle was expected because metaldehyde is a molluscicide.

The acute risk was not assessed for terrestrial plants and plants growing in semi-aquatic areas because no data were available to the USEPA.

Exposure and Risk to Aquatic Wildlife

To assess the risk to aquatic species, the USEPA used the risk quotient (RQ) method. The RQ is an index of the potential adverse effects and is calculated by dividing the estimated environmental concentration (EECs) with the most sensitive toxicity endpoint values. The RQ is then compared with the USEPA's LOC to identify when the potential adverse effects are of concern to the USEPA. In this assessment, the application method considered was by ground broadcast of metaldehyde granules to soil.

Exposure of aquatic organisms to metaldehyde was assumed to occur through direct contact with contaminated water. Exposure concentrations of metaldehyde for aquatic ecosystems resulting from granular application of metaldehyde were estimated by the USEPA using a Tier 1 computer model. The model assumed multiple applications per season and annual application rates from 4.5 kg a.i./ha (berries) to 47 kg a.i./ha (ornamentals). Peak concentrations were used to derive RQs for acute exposure.

RQs for acute exposure to freshwater fish were below the acute risk LOC for all application rates.

Acute RQs were not calculated for freshwater invertebrates since no treatment-related effects were observed at the highest concentration of metaldehyde tested on *Daphnia magna*.

No acceptable toxicity data were available to the USEPA to assess chronic risks to freshwater fish and invertebrates.

No data on toxicity of metaldehyde to non-target freshwater mollusks were available to the USEPA. However, since metaldehyde is a molluscicide, it was expected that there would be risk to non-target freshwater mollusks.

No data were available to the USEPA to characterize effects to estuarine/marine fish/invertebrates following either acute or chronic metaldehyde exposure. However, results of an open literature field study with the brackish pond water snail and an open literature laboratory study with the Pacific oyster indicated that metaldehyde was likely to be at least moderately toxic to estuarine/marine invertebrates.

No toxicity data were available to the USEPA to assess acute or chronic exposures to aquatic plants.

Conclusion
The USEPA conclusions are considered applicable to the Canadian use pattern and the risk-reduction measures recommended by the USEPA should be applied to Canadian metaldehyde products as follows.

- As in the United States, product labels must prominently display prohibition against broadcast, foliar, turf and dichondra applications.

- Use sites, maximum application rates, maximum application numbers and minimum retreatment intervals must be restricted to those supported under the reregistration program in the United States, as listed in Appendix III. The current Canadian commercial use on ornamentals (0.9 kg a.i./ha, six applications/year) is considered adequate. However, the wording "repeat treatment as necessary to maintain control" must be changed to reflect the USEPA-accepted 21 days minimum treatment interval.

- As required in the United States, Canadian granular products must not be formulated at a rate of fewer than 35 pellets per gram, which is a measure to reduce the potential for ingestion of pellets of metaldehyde products by animals.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances*

Management Policy, were taken into account during the re-evaluation of metaldehyde. The PMRA has reached the following conclusions.

- Metaldehyde is not bioaccumulative. The *n*-octanol–water partition coefficient (log K_{ow}) is 0.12 at neutral pH, and is below the TSMP Track 1 cut-off criterion of ≥5.0. Metaldehyde was not persistent. The aerobic soil half-life was found to be 67 days, which is below the TSMP Track 1 criterion of 180 days. Metaldehyde does not meet all Track 1 criteria; thus, it is not a candidate for Track 1 classification.

- Based on a review of the available chemistry information (see Section 2.1), the technical class product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

4.0 Proposed Re-evaluation Decision

Metaldehyde products are currently labelled for many uses that are not being supported by the registrant. Only those uses that are supported by the registrant have been re-evaluated. Among the uses, only those that were eligible for reregistration in the United States are considered acceptable for continued registration by the PMRA. These uses are described in Appendix III.

All other uses currently on metaldehyde product labels together with those determined not to be eligible for continued registration in Canada must be deleted from the product labels.

In addition, granular products must be formulated at a rate of greater that 35 pellets per gram to reduce the chances of being mistakenly taken up by animals as food.

All domestic class end-use products containing metaldehyde must be formulated with a bittering agent approved by the PMRA at a sufficient amount to deter ingestion by children and domestic animals.

No additional data are being requested at this time.

5.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for metaldehyde (Docket ID OPP-2005-0231) is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

µg	microgram(s)
a.i.	active ingredient
aPAD	acute population adjusted dose
bw	body weight
C	commercial
cm	centimetre(s)
cPAD	chronic population adjusted dose
D	domestic
DACO	data code
EDWC	estimated drinking water concentration
FQPA	*Food Quality Protection Act*
ha	hectare(s)
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LOC	level of concern
MA	manufacturing concentrate
mg	milligram(s)
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
Q_1^*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient
RTU	ready-to-use
SF	safety factor
T	technical
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing Metaldehyde as of February 2008

Registrant	Registrant Code	Registration Number	Guarantee	Product Name	Formulation Type	Class
SPECTRUM BRANDS IP INC	SJB	8819	2.75%	C-I-L SLUG KILLER PELLETS	PELLETS (PE)	D
MATSON LLC	MBS	20785	4%	CORRY'S LIQUID SLUG & SNAIL CONTROL	SUSPENSION (SU)	D
SPECTRUM BRANDS IP INC	SJB	20785.01	4%	LATER'S LIQUID SLUG & SNAIL CONTROL	SUSPENSION (SU)	D
MATSON LLC	MBS	997	2%	CORRY'S SLUG & SNAIL DEATH	GRANULAR (GR)	D
MATSON LLC	MBS	25565	2%	CORRY'S SLUG & SNAIL PELLETS	PELLETS (PE)	D
AMVAC CHEMICAL CORPORATION	AMV	26650	4%	DEADLINE M-PS	PELLETS (PE)	C
KING HOME & GARDEN INC.	KHG	28287	2.75%	KING SLUG & SNAIL PELLETS	PELLETS (PE)	D
KING HOME & GARDEN INC	KHG	25421	2.75%	KING SLUG PELLETS	PELLETS (PE)	D
SPECTRUM BRANDS IP INC	SJB	179	2.25%	META SLUG & SNAIL KILLER BAIT	PARTICULATE (PT)	D
SPECTRUM BRANDS IP INC	SJB	8169	2.75%	META SLUG & SNAIL PELLETS	PELLETS (PE)	D
LONZA INC.	LOZ	22689	98%	META-METALDEHYDE TECHNICAL MOLLUSCICIDE	DUST (DU)	T
HACCO INC.	HOC	24045	2.75%	SLUG PELLETS	PELLETS (PE)	D
SPECTRUM BRANDS IP INC	SJB	2791	6.5%	SLUG-EM MOLLUSCICIDE (SLUG BAIT)	PARTICULATE (PT)	D
NU-GRO PR INC.	NGI	27113	2.75%	WILSON SLUG BAIT (FOR REPACKAGING)	PELLETS (PE)	MA
SPECTRUM BRANDS IP INC	SJB	25908	2%	WILSON SLUGOUT MEAL	GRANULAR (GR)	D
SPECTRUM BRANDS IP INC	SJB	10304	2.75%	WILSON SLUGOUT PELLETS	PELLETS (PE)	D

D = Domestic; C = Commercial; T = Technical; MA = Manufacturing Concentrate

Appendix II Toxicological Endpoints for Metaldehyde Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	Target UF/SF or MOE or Q_1* [a]
Acute dietary (all populations)	Oral NOAEL = 75	Developmental toxicity in rats	UF = 1000 FQPA SF = 1
Chronic dietary (all populations)	Oral NOAEL = 10	Chronic oral toxicity study in dog	UF = 1000 FQPA SF = 1
Short-term incidental oral (1–30 days)	Oral NOAEL = 30	Chronic oral toxicity study in dog	Residential LOC for MOE = 1000
Intermediate-term incidental oral (1–6 months)	Oral NOAEL = 10	Chronic oral toxicity study in dog	Residential LOC for MOE = 1000
Short-term inhalation (1–30 days)	Oral NOAEL = 30 (inhalation absorption rate = 100%)	Chronic oral toxicity study in dog	Residential LOC for MOE = 1000 Occupational LOC for MOE = 100
Intermediate-term inhalation (1–6 months)	Oral NOAEL = 10 (inhalation absorption rate = 100%)	Chronic oral toxicity study in dog	Residential LOC for MOE = 1000 Occupational LOC for MOE = 100
Long-term inhalation (>6 months)	Oral NOAEL = 10 (inhalation absorption rate = 100%)	Chronic oral toxicity study in dog	Residential LOC for MOE = 1000 Occupational LOC for MOE = 100
Cancer (oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenic Potential" A quantification of cancer risk for metaldehyde was not performed.		

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments. Q_1* refers to cancer potency factor.

Appendix III Uses and Use Parameters Supported by the PMRA as a Result of the Re-evaluation Decision

Use Site	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications/Year	Minimum Application Interval (day)
Domestic Class End-Use Products			
Cole crops and other leafy greens	1.1	3	14
Lettuce	1.1	3	14
Tomato	1.1	3	14
Strawberry	1.1	3	14
Blueberries	0.9	3	14
Caneberries and other berries	0.9	3	14
Artichokes (perennials)	1.1	6	18
Artichokes (annuals)	1.1	2	18
Ornamentals	1.1	6	21
Commercial Class End-Use Products			
Spinach	1.1	3	14
Cabbage	1.1	3	14
Lettuce	1.1	3	14
Tomato	1.1	3	14
Strawberry	1.1	3	14
Blackberries	0.9	3	14
Ornamentals	1.1	6	21

Appendix IV Label Amendments for the Commercial Class End-Use Product Containing Metaldehyde

The label of the commercial class end-use product in Canada must be amended as follows to further protect workers and the environment.

I) In the **PRECAUTIONS** section:

The statement

> This product is toxic to dogs, birds and other wildlife. Dogs and other animals are attracted to metaldehyde baits and poisoning with fatalities may result.

must be replaced with:

> This product can be harmful to children and fatal to domestic animals when ingested. Children and dogs may be attracted to the product. Application of this product is prohibited unless children and domestic animals can be excluded from the treated area from the start of the application until applied material is no longer visible.

The paragraph

> Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

must be replaced with:

> Toxic to aquatic organisms
>
> Toxic to birds
>
> Toxic to small wild mammals
>
> To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.
>
> Avoid application when heavy rain is forecast.
>
> Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

The following statement must be added.

> DO NOT enter or allow worker entry into treated areas for 12 hours following application.

II) In the **FIRST AID** section:

The following statements must be included.

Seek medical care as soon as possible after exposure. For incidents involving animals, seek veterinary care as soon as possible after exposure. Have the product container or label with you when you call a poison control centre or doctor or veterinarian, or when going for treatment.

Metaldehyde is a systemic toxin. There is no antidote. The following instructions are not intended for laypeople. There is no home treatment. Exposed individuals and animals should receive emergency care as quickly as possible.

TOXICOLOGICAL INFORMATION:

HUMANS: Dust inhalation is usual route of accidental exposure; the product is rarely ingested except by children. Treatment is symptomatic and supportive. Monitor severe exposures closely: seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature have been reported.

PETS: Animals typically are exposed via ingestion. Treatment is symptomatic and supportive. If significant ingestion suspected, and the animal is asymptomatic, consider induction of emesis or gastric lavage and administration of activated charcoal, cathartic and enema to limit absorption. Monitor asymptomatic and symptomatic animals closely. Treat seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature. Monitor liver function post recovery.

III) The **DIRECTIONS FOR USE** section.

- Must be amended to indicate that broadcast applications and applications to turf are prohibited.

- Must be amended to allow use only on the crops and use sites identified in Appendix III. Use instructions must be consistent with the maximum application rate, maximum number of applications per growing season, and minimum retreatment intervals listed in Appendix III. Reference to any other crop or use sites must be removed from the end-use product label.

IV) Under the **STORAGE** section:

The following statements must be included.

This product can be harmful to children and fatal to dogs and other domestic animals if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

Appendix V Label Amendments for the Domestic Class End-Use Products Containing Metaldehyde

I) On the front panel:

The following signal words and the corresponding warning symbol must be included on all domestic class product labels.

CAUTION POISON

All product labels must contain a graphic that depicts the prohibition on allowing children and domestic animals access to treated areas. The required graphic is in the form of a red circle with the words "Children" and "Pets" within the circle and with a red bar running diagonally through it from upper left to lower right.

The following specific warning statements must be added to the label in close association to the above graphic.

Keep out of reach of children and domestic animals.

II) In the **PRECAUTIONS** section:

The following specific warning statements must be included.

This product may be harmful to children and fatal to domestic animals if ingested. Children and dogs may be attracted to metaldehyde products and their packaging. Keep children and pets out of treated areas from the start of application until the applied product is no longer visible. For additional precautionary measures, see **DIRECTIONS FOR USE** and **STORAGE DISPOSAL**.

Toxic to aquatic organisms. Do not apply product near water (including garden ponds) or storm drains. Do not apply if heavy rain is expected. Apply this product only around gardens and ornamental plants.

Toxic to birds

Toxic to small wild mammals

For granular or pelletized product, add:

Collect and remove any product that is spilled.

III) In the **FIRST AID** section:

The following specific warning statements must be included.

Seek medical care as soon as possible after exposure. For incidents involving animals, seek veterinary care as soon as possible after exposure. Have the product container or label with you when you call a poison control centre or doctor or veterinarian, or when going for treatment.

Metaldehyde is a systemic toxin. There is no antidote. The following instructions are not intended for laypeople. There is no home treatment. Exposed individuals and animals should receive emergency care as quickly as possible.

TOXICOLOGICAL INFORMATION:

HUMANS: Dust inhalation is usual route of accidental exposure; the product is rarely ingested except by children. Treatment is symptomatic and supportive. Monitor severe exposures closely: seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature have been reported.

PETS: Animals typically are exposed via ingestion. Treatment is symptomatic and supportive. If significant ingestion suspected, and the animal is asymptomatic, consider induction of emesis or gastric lavage and administration of activated charcoal, cathartic and enema to limit absorption. Monitor asymptomatic and symptomatic animals closely. Treat seizures, electrolyte imbalances, acidosis, dehydration, and increased body temperature. Monitor liver function post recovery.

IV) In the **DIRECTIONS FOR USE** section.

The label must be amended to include the following statements:

Keep people and pets out of the area during application.

Application of this metaldehyde product is prohibited unless children and domestic animals can be excluded from the treated areas from the start of application until the applied product is no longer visible.

Applications to turf and dichondra are prohibited. Application is permitted only to non-turf areas (i.e. on soil or mulch) directly surrounding plants listed for use on the label.

Broadcast and foliar applications of this product are prohibited. Application is permitted only as a barrier around gardens or individual plants. Application is prohibited within 30 cm of vegetable plants or fruit-bearing plants not listed on this label.

Avoid applying pellets in piles that may attract pets.

Registrants are encouraged to include the following cultural practice statements

Certain cultural practices may reduce damage from snails and slugs. These practices include:

- eliminating hiding places by removing leaf litter and debris in the garden
- removing slugs and snails during daylight hours from nearby leaf litter, mulch and other protected areas
- watering in the morning to reduce humidity during the night when snails and slugs are active

End-use product labels must be amended to allow use only on the crops and use sites identified in Appendix III. Use instructions must be consistent with the maximum application rate, maximum number of applications per growing season and minimum retreatment intervals listed in Appendix III. Reference to any other crop or use site must be removed from end-use product labels. For products that have uses on pathways (i.e. Reg. No. 179, Reg. No. 8169 and Reg. No. 8819), those uses must be removed from the product labels.

Application rates must be provided in user-friendly terms, for example, "Apply pellets as a barrier around plants by distributing pellets evenly in a line at a rate of X tablespoons of product per X linear metre."

V) In the **STORAGE** section:

Label must be amended to include the following statements.

This product can be harmful to children and fatal to domestic animals if ingested. Dogs have been known to ingest metaldehyde after opening or tearing packaging. Store this product in its original packaging, in a cool, secure location, and out of reach of children and pets.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

References

PMRA 1467154 TGAI Chemistry. DACO: 2.99

PMRA 1467160 TGAI Chemistry. July 30, 1992, DACO: 2.99